# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

W. R. GRACE & COCONN.,	
Plaintiff,	
v.	C.A. No. 20-1098-GBW-JLH
ELYSIUM HEALTH, INC.,	
Defendant.	

## **FINAL JURY INSTRUCTIONS**

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#### 1.1 INTRODUCTION

Members of the jury: You have all of the evidence you will hear and see in this case. It is now time for me to instruct you about the law that you must follow in deciding this case. Please listen very carefully to everything I say. You must follow all of my instructions, including the ones I gave to you on Monday at the beginning of the case and the ones I gave during trial. You must not single out some instructions and ignore others. They are all important.

I will start by explaining your duties and the general rules that apply in every civil case.

Then I will explain some rules that you must use in evaluating particular testimony and evidence.

Then I will explain the positions of the parties and the law you will apply in this case. Finally, I will explain the rules that you must follow during your deliberations and the possible verdicts that you may return.

You will have a written copy of these instructions with you in the jury room for your reference during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case.

#### 1.2 JUROR'S DUTES

You have two main duties as jurors. The first is to decide what the facts are from the evidence that you saw and heard in court. Deciding what the facts are is your job, not mine.

Nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. Do not guess or speculate, and do not be influenced in any way by any bias, personal feeling of, sympathy for, or prejudice against, either side in this case.

Your second duty is to take the law that I give you, apply it to the facts, and decide which party should prevail on each issue. As I will tell you, there are different burdens of proof—the standard for deciding whether a party has proven its position on specific issues—and you must apply those burdens of proof as you decide each issue. It is my job, however, to explain the legal principles that must guide you in your decisions, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. All of the instructions are important, and you should consider them together as a whole. Perform these duties fairly.

#### 1.3 SUMMARY OF CONTENTIONS AND PATENT ISSUES

During the jury-selection process, I advised you that this is a civil action arising under the patent laws of the United States. The parties in this case are W.R. Grace & Co.-Conn., which has been referred to as "Grace" or "Plaintiff," and Elysium Health, Inc., which has been referred to as "Elysium" or "Defendant." There are two patents for you to consider in this case, which I may—and others during trial have—collectively refer to as the "Asserted Patents" or "Patents-in-Suit." They are:

- U.S. Patent No. 10,323,058, also called the '058 patent;
- and
- U.S. Patent No. 10,189,872, also called the '872 patent.

You may also have heard the first patent, the '058 patent, referred to as the "Form I Patent" and the '872 patent referred to as the "Form II Patent."

I will first give you a summary of each side's contentions in this case. I will then provide you with detailed instructions on what each side must prove to win on each of its contentions.

Grace alleges that Elysium infringes the '058 and '872 patents by selling a product that Grace contends is covered by claims 1, 2 and 21 of the '058 patent, and claims 1, 6, and 15 of the '872 patent. I will refer to these claims as the "Asserted Claims."

Grace contends that it has suffered damages as a result of Elysium's infringement and seeks to recover a reasonable royalty from Elysium. Grace also contends that Elysium's infringement was willful.

Elysium denies that it has infringed the Asserted Claims, willfully or otherwise. Elysium also contends that the two Asserted Patents are invalid. Elysium denies that Grace is entitled to any damages and also disputes Grace's method of calculating damages.

Your job is to decide whether Elysium has proven that any of the Asserted Claims or Patents are invalid and whether Grace has proven that Elysium infringed any Asserted Claims of the Patents-in-Suit that you have not found invalid.

If you decide that any claim of the Asserted Patents has been infringed and that claim is not invalid, then you will need to decide the amount of any money damages to be awarded and whether that infringement was willful.

#### 1.4 BURDENS OF PROOF

In any legal action, facts must be proven by a required standard of evidence, known as the "burden of proof." For every issue you must decide in this case, either Grace or Elysium bears the burden of proof. The party who bears the burden of proof on an issue bears the burden of persuading you to find in their favor, and if they do not meet the burden of proof, then you must find that they have not prevailed on that issue. In this case, there are two different burdens of proof.

One of these burdens of proof is called a "<u>preponderance of the evidence</u>." Grace has the burden of proving that Elysium infringed the Asserted Patents by a preponderance of the evidence. Grace also has the burden of proving the amount of damages it should receive to compensate it for any infringement by a preponderance of the evidence.

A "preponderance of the evidence" means that Grace must produce evidence that, when considered in light of all of the facts, leads you to believe that what Grace claims is more likely true than not true. To put it differently, if you were to put Grace's evidence and Elysium's evidence on opposite sides of a scale, the evidence supporting Grace's infringement claims would have to outweigh Elysium's evidence of non-infringement—the scale would have to tip in favor of Grace.

The other burden of proof you must consider is called "<u>clear and convincing evidence</u>."

Clear and convincing evidence means that it is highly probable that a fact is true. Proof by clear and convincing evidence is a higher burden than proof by a preponderance of the evidence. In

this case, Elysium has the burden of proving that the Asserted Claims of the Patents-in-Suit are invalid by clear and convincing evidence.

Some of you may have heard the phrase "proof beyond a reasonable doubt." It is often referred to in books, shows and movies. That burden of proof applies only in criminal cases, and you should therefore not consider it in this case.

#### 1.5 EVIDENCE DEFINED

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence you should consider in this case includes only what the witnesses said while they were testifying under oath (including deposition testimony that has been read to you or played by video), the exhibits that I allowed into evidence, the stipulations that the lawyers agreed to, and the facts that I have judicially noticed. Nothing else is evidence. The lawyers' statements and arguments are not evidence. Their questions and objections are not evidence. Their statements and arguments are intended to help you review the evidence presented. If you remember the evidence differently from the way the attorneys described it, you should rely on your own recollection or ask that it be re-read to you. My legal rulings are not evidence. Any of my comments and questions are not evidence.

During the trial, I may not have let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And sometimes I may have ordered you to disregard things that you saw or heard, or that I struck from the record. You must completely ignore all these things. Do not speculate about what a witness might have said or what an exhibit might have shown.

Speculation is not evidence, and you are bound by your oath not to let speculation influence your decision in any way.

At certain points during this trial, I had discussions with the attorneys here at the bench outside of your hearing, or called a recess to and talk with them while you were out of the courtroom. This happened because, during a trial, things often arise that do not involve the jury. You must likewise ignore these discussions and you must not let speculation of these discussions influence your decision in any way.

You must not conduct any independent research, investigation, or experiments about the case or its subject matter on your own. In other words, you should not, for instance, conduct internet searches or do other investigations. Make your decision based only on the evidence, as I have defined it here, and nothing else.

## 1.6 DIRECT AND CIRCUMSTANTIAL EVIDENCE

There are two kinds of evidence: direct evidence and circumstantial evidence. Direct evidence is direct proof of a fact, such as the testimony of an eyewitness. For example, if a witness testified that she saw it raining outside, and you believed her, that would be direct evidence that it was raining.

Circumstantial evidence is indirect proof of a fact. In other words, it is proof of facts from which you may infer or conclude that other facts exist. For example, if someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

The law makes no distinction between the weight that you should give to either direct or circumstantial evidence, but simply requires that you find facts from all the evidence in the case. It is your job to decide how much weight to give the direct and circumstantial evidence. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it fairly deserves.

#### 1.7 CONSIDERING THE EVIDENCE

You should use your common sense in weighing the evidence. Consider the evidence in light of your everyday experience with people and events and give it whatever weight you believe it deserves.

You may, unless I otherwise instructed you, consider the testimony of all the witnesses and all the exhibits received and admitted into evidence for any issue you must decide in this case, regardless of who may have called that witness or introduced the exhibit.

And while you should consider only the evidence in this case, you are permitted to draw such reasonable inferences from that evidence as you feel are justified in light of your common sense and everyday experience. In other words, you may make deductions and reach conclusions that reason and common sense lead you to draw from the facts that have been established by the evidence in the case.

#### 1.8 CREDIBILITY OF WITNESSES

You are the sole judges of each witness's credibility. You should consider: each witness's means of knowledge, strength of memory, and opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

If you find the testimony to be contradictory, you must try to reconcile it, if reasonably possible, so as to make one harmonious story of it all. But if you cannot do this, then it is your duty and privilege to believe the portions of testimony that, in your judgment, are most believable and disregard any testimony that, in your judgment, is not believable.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact, or whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony the witness gave at the trial. You have the right to distrust such a witness's testimony in other particulars and you may reject some or all of the testimony of that witness or give it whatever weight and credit you think it deserves.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may forget some things or remember other things

inaccurately. If a witness has made a misstatement, you must consider whether it was an innocent lapse of memory or an intentional falsehood, and that may depend upon whether it concerns an important fact or an unimportant detail. This instruction applies to all witnesses, including expert witnesses and witnesses who provided testimony by deposition.

## 1.9 NUMBER OF WITNESSES

Sometimes jurors wonder if the number of witnesses who testified makes any difference.

Do not make any decisions based on the number of witnesses who testified. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

#### 1.10 EXPERT WITNESSES

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession, or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience. However, you are not required to accept any expert's opinion. As with any other witness, it is up to you to decide whether or not to rely upon it.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing the testimony of any witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject some or all of the testimony of experts, just as with any other witness.

#### 1.11 DEPOSITION TESTIMONY

During the trial, certain testimony was read to you from a deposition transcript or presented to you through playing video excerpts of the deposition. Before trial, attorneys questioned witnesses under oath, and a videographer as well as a court reporter, like the ones we have had here during trial, recorded those proceedings. That is the deposition testimony you have heard.

Even though a deposition happens out of court, it is entitled to the same consideration as the testimony of a witnesses who personally appeared in court. You should not attribute any significance to the fact that a deposition was read to you or played by video. Accordingly, you should judge the credibility and weigh the importance of deposition testimony to the best of your ability just as if the witness had testified in person in open court.

In addition, you may have noticed that certain deposition testimony was edited or cut to exclude irrelevant testimony, and that may even have made the testimony appear jumpy or disjointed. You should not attribute any significance to the fact that the deposition videos may appear to have been edited or that only certain portions of the deposition transcripts were read.

#### 1.12 DEMONSTRATIVE EXHIBITS

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. You will have these admitted exhibits in the jury room for your deliberations.

The remainder of the exhibits (including charts, models, reproductions, PowerPoint presentations, and animations) were offered to help illustrate the testimony of the various witnesses. These are called "demonstrative exhibits." They have not been admitted as evidence and should not be considered as evidence. Rather, it is the testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.

#### 1.13 USE OF NOTES

You may use notes you took during trial to assist your memory. However, you should use caution in consulting your notes. There is a tendency to attach undue importance to matters that you have written down. Some testimony that is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented.

Therefore, you are instructed that your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence and are by no means a complete outline of the proceedings or a list of the highlights of the trial. Above all, your memory should be your greatest asset when it comes time to deliberate and render a decision in this case.

#### **B1. SUMMARY OF CONTENTIONS**

#### 1.1 SUMMARY OF CONTENTIONS

As I did at the start of the case, I will first give you a summary of each side's contentions in this case. I will then provide you with detailed instructions on what each side must prove to win on each of its contentions.

As I previously told you, Grace seeks money damages from Elysium for allegedly infringing the Asserted Patents by selling a product that Grace argues infringes claims 1, 2 and 21 of the '058 patent, and claims 1, 6, and 15 of the '872 patent. I will refer to these claims as the Asserted Claims. The product that Grace alleges to infringe is called BASIS®. I will refer to this product as Elysium's Product. Grace also contends that Elysium's infringement was willful.

Elysium denies that it has infringed the asserted claims and argues that the asserted claims are invalid. Elysium denies that Grace is entitled to any damages. Elysium also denies that any infringement was willful.

Your job is to decide whether Elysium has infringed the Asserted Claims and whether any of the Asserted Claims are invalid. If you decide that one or more of the Asserted Claims have been infringed and are not invalid, you will then need to decide what amount of money damages, if any, should be awarded to Grace to compensate it for the infringement as well as how those damages are calculated. You will also need to make a finding as to whether the infringement was willful. Whether or not you decide that any infringement was willful, that decision should not affect any damage award you make. I will take willfulness into account later.

#### **B2. CLAIM CONSTRUCTION**

#### 2.1 INTERPRETATION OF CLAIMS

At the beginning of the trial, I gave you some general information about patents and the patent system and a brief overview of the patent laws relevant to this case. I will now give you more detailed instructions about the patent laws that specifically relate to this case. As a reminder, if you would like to review my instructions at any time during your deliberations, you will have your copy available to you in the jury room.

Before you decide whether Elysium has infringed the asserted claims or whether the asserted claims are invalid, you will need to understand the patent claims. Patent claims are numbered sentences at the end of a patent that define what the patent covers. The figures and text in the rest of the patent provide a description and/or examples of the invention and provide context for the claims, but it is the claims themselves that define the breadth of the patent's coverage.

To know what a claim covers, you must consider what a claim sets forth, in words, as a set of requirements. Each claim sets forth its requirements in a single sentence. The requirements of a claim are often referred to as "claim elements" or "claim limitations." What a patent covers is assessed claim-by-claim. When a product meets all of the requirements of a claim, the claim is said to "cover" that product, and that product is said to "fall" within the scope of that claim. In other words, a claim covers a product where each of the claim elements or limitations is present in that product.

You will first need to understand what each claim covers in order to decide whether or not there is infringement of the claim and to decide whether or not the claim is invalid. The first step is to understand the meaning of the words used in the patent claim. It is my job as judge to explain to you the meaning of any language in the claims that needs interpretation.

As I explained to you at the start of the case, the Court has defined some of the language in the patent claims involved in this case. Those definitions are in your notebooks and attached to the end of these instructions as "C-2 Appendix." You must accept those definitions as correct. This interpretation of the language should not be taken as an indication that I or this Court have a view regarding the issues of infringement and invalidity. The decisions regarding infringement and invalidity are yours to make.

For any words in the claim for which I have not provided you with a definition, you should apply the ordinary meaning of those terms in the field of the patent.

### **B2.** CLAIM CONSTRUCTION

#### 2.2 INDEPENDENT AND DEPENDENT CLAIMS

Claims can be stated in two different ways in a patent. The first way a patent claim can be stated is in the form of an "independent" claim. An "independent" claim sets forth all of the requirements that must be met in order for an accused product to be covered by that claim, and thus infringe that claim. An independent claim is read alone to determine its scope and does not refer to any other claim of the patent. In this case, claim 1 of the '058 patent and claim 1 of the '872 patent are independent claims. The other Asserted Claims are not independent claims, but rather they are dependent claims.

The second way a claim can be stated is in the form of a "dependent" claim. A dependent claim does not itself recite all of the requirements of the claim but instead incorporates the requirements of another claim and adds its own additional requirements. In this way, the claim "depends" on another claim. The easiest way to identify a dependent claim is that it explicitly refers to another claim in the patent by claim number.

To determine what a dependent claim covers, it is necessary to look at both the dependent claim and the other claim on which it depends and refers to. For example, claim 20 of the '058 patent is a dependent claim because it incorporates the requirements of claim 1 when it ends with "the crystalline Form I according to claim 1." As a result, claim 20 of the '058 patent includes all the requirements of claim 1 and the additional requirements specifically set forth in claim 20. Claim 21 then depends from Claim 20, based upon it reciting "The method according to claim 20 wherein ..."—and so that means claim 21 of the '058 patent includes all the requirements of

claims 20, and therefore claim 1, as well as the additional requirements specifically set forth in claim 21.

An accused product is only covered by, and therefore infringes, a dependent claim if the accused product meets all of the requirements of both the dependent claim and the independent claim from which the dependent claim depends. If you find that an independent claim is not infringed, then the dependent claims that depend on that independent claim are not infringed either.

Likewise, each claim must be separately assessed for validity. For an independent claim, all its requirements must be considered in deciding its validity. For a dependent claim, all its requirements plus the requirements of the independent claim on which it depends must be considered for that dependent claim's validity. If you find that an independent claim is invalid, that does not necessarily mean that the claims that depend on that claim are invalid. You must separately consider the validity of the dependent claims in view of their additional limitations to determine if the additional limitations in the dependent claims distinguish the validity of the dependent claims from the independent claims.

#### 3.1 INFRINGEMENT-GENERALLY

I will now instruct you on the rules you must follow in deciding whether Grace has proven that Elysium infringed any Asserted Claims. To prove infringement, Grace must persuade you with a preponderance of the evidence, meaning that it is more likely than not that Elysium has infringed one or more of the Asserted Claims.

Infringement is assessed on a claim-by-claim basis—patents cannot be infringed, only the claims of the patents. Therefore, there may be infringement as to one claim but no infringement as to another.

In this case, there are three possible ways that a claim may be infringed. The three types of infringement are called: (1) direct infringement; (2) active inducement; and (3) contributory infringement. Active inducement and contributory infringement can also be referred to as "indirect infringement." There cannot be indirect infringement without someone else engaging in direct infringement.

In this case, Grace has alleged that Elysium directly infringes the Asserted Patents. In addition, Grace has alleged that Elysium's customers directly infringe the Asserted Patents and so Elysium is liable for actively inducing this alleged direct infringement and/or contributing to that alleged direct infringement by Elysium's customers.

I will now explain each of these types of infringement in more detail, but you as jurors must compare each claim to the evidence to see if there is direct or indirect infringement by Elysium.

#### 3.2 DIRECT INFRINGEMENT

To determine whether a claim has been directly infringed, you must compare the Accused Product with the claims Grace asserts are infringed, using my instructions as to the meaning of the terms contained in the claims.

You must compare the Accused Product with the patent claim and determine whether every requirement of the claim is included in that product. If so, the Accused Product infringes that claim. You, the jury, make this decision.

Grace may prove infringement using direct evidence, circumstantial evidence, or any method of analysis that supports the fact of infringement.

Intent is not required for direct infringement. Whether or not Elysium knew its product infringed or even knew of the Asserted Patents is irrelevant.

#### 3.3 INDIRECT INFRINGEMENT—ACTIVE INDUCEMENT

Grace alleges that Elysium is liable for infringement by actively inducing Elysium's customers to directly infringe certain claims of the Asserted Patents. This is a form of indirect infringement. As with direct infringement, you must determine whether there has been active inducement on a claim-by-claim basis.

To prove that Elysium actively induced others to infringe the Asserted Claims, Grace must prove by a preponderance of the evidence:

- (1) that the acts actually carried out by Elysium's customers directly infringe that claim;
- (2) that Elysium took action during the time the Asserted Patents were in force that was intended to cause and led to the infringing acts by its customers; and
- (3) that Elysium was aware of each Asserted Patent that Grace claims Elysium was actively inducing infringement of, and that Elysium either knew that the acts, if taken, would constitute direct infringement of that patent or that Elysium was willfully blind to its actions causing direct infringement. Willful blindness means that even though Elysium may not have actually knew of the direct infringement, Elysium believed there was a high probability that the acts by its customers would directly infringe the Asserted Patents Grace claims Elysium was actively inducing infringement of, and Elysium took deliberate steps to avoid learning of those facts.

If you find that Elysium was aware of a patent but believed that the acts it encouraged did not infringe that patent, Elysium cannot be liable for active inducement. Grace also cannot meet

its burden of showing Elysium actively induced infringement if Elysium was either unaware of or not willfully blind to the existence of the Asserted Patents.

You may find induced infringement based on circumstantial evidence of inducement, such as advertisements or user manuals, directed to a class of third-party direct infringers, such as customers or end-users. Grace does not have to show specific evidence that any individual third-party direct infringer was actually persuaded to infringe by that material.

#### 3.4 INDIRECT INFRINGEMENT—CONTRIBUTORY INFRINGEMENT

Grace argues that Elysium is liable for contributory infringement by contributing to the direct infringement of the Asserted Patents by its customers. As with direct infringement, you must determine contributory infringement on a claim-by-claim basis.

To prove contributory infringement, Grace must prove by a preponderance of the evidence:

- (1) that Elysium sells, offers to sell, or imports within the United States a component of a product, material, or apparatus for use in a process, during the time the Asserted Patents are in force;
- (2) that the component, material, or apparatus is not a staple article or commodity of commerce suitable for substantial noninfringing use;
- (3) that the component, material, or apparatus constitutes a material part of the invention;
- (4) that Elysium knew of the Asserted Patents and knew that the component, material, or apparatus was especially made or adapted for use in infringing the claim; and
- (5) that Elysium's customers used the component, material, or apparatus to directly infringe a claim.

#### 3.5 WILLFUL INFRINGEMENT

In this case, Grace argues that Elysium willfully infringed the Asserted Patents. If you have decided that Elysium has infringed one or more valid claims, then you must go on and address the additional issue of whether or not this infringement was willful.

To prove willful infringement of a claim, Grace must persuade you that it is more likely true than not true that Elysium intentionally infringed at least one asserted claim of the Asserted Patents. You must base your decision on Elysium's knowledge and actions at the time of infringement. Evidence that Elysium had knowledge of the patent at the time of infringement by itself is not sufficient to show willfulness. Rather, to show willfulness, you must find that Elysium engaged in additional conduct evidencing a deliberate disregard of Grace's patent rights at issue in this case.

In deciding whether Elysium willfully infringed, you may consider all of the facts surrounding the infringement including: whether Elysium intentionally copied Grace's patented technology in developing Elysium's Product; whether Elysium knew, or should have known, that its conduct involved an unreasonable risk of infringement of the Asserted Patent; and whether Elysium had a reasonable belief that at the time of infringement that its products did not infringe the Asserted Patent or that the patent was invalid.

As I mentioned before, if you determine that any infringement was willful, you may not allow that decision to affect the amount of any damages award you give for infringement.

**B4. VALIDITY** 

#### 4.1 INVALIDITY - BURDEN OF PROOF

I will now instruct you on the rules you must follow in deciding whether Elysium has proven that the asserted claims are invalid. Before discussing the specific rules, I want to remind you about the standard of proof that applies to this defense. Patents are presumed to be valid. This is because issued patents have been examined by patent examiners at the U.S. Patent and Trademark Office, and the examiners are presumed to have performed their duties properly until proven otherwise. To prove invalidity of any patent claim, Elysium must persuade you with clear and convincing evidence, meaning that it is highly probable that the claim is invalid. This is a higher burden of proof than the "preponderance of the evidence" standard that you applied in your consideration of infringement.

You must consider the claims the same way for determining infringement as for determining invalidity. You must apply the claim language consistently, as I have construed the claim terms, and treat the language in the same manner for issues of infringement and for issues of invalidity.

In reaching your decision on validity, you can also considering whether you have heard evidence that patent examiners at the U.S. Patent and Trademark Office had no opportunity to evaluate before granting the Asserted Patents.

**B4. VALIDITY** 

#### 4.2 INVALIDITY – PERSPECTIVE OF ONE OF ORDINARY SKILL IN THE ART

The question of invalidity of a patent claim is determined from the perspective of a hypothetical "person of ordinary skill in the art" in the field of the asserted invention as of the patent's effective filing date.

For your determinations, I instruct you that you should consider the issues premised upon the '058 patent having an effective filing date of July 24, 2014 and the '872 patent having an effective filing date of March 9, 2015. These are the earliest priority applications that led to each of these patents issuing. You may have noticed that one year earlier has been called the "critical date" for each patent, which I will get to in a moment.

The "person of ordinary skill in the art" is sometimes referred to as a "POSA." In deciding the level of ordinary skill this hypothetical person would have, you should consider all the evidence introduced at trial, including:

- (1) the levels of education and experience of persons working in the field;
- (2) the types of problems encountered in the field;
- (3) prior art solutions to those problems;
- (4) rapidity with which innovations are made; and
- (5) the sophistication of the technology.

The level of skill possessed by an inventor is not a proper measure of the level of skill possessed by a POSA. While an inventor may be a POSA, an inventor is not necessarily a POSA and may have more or less knowledge than the hypothetical POSA.

A POSA would have had a bachelor's degree in chemistry or a closely related discipline and at least 4 years of experience crystallizing and characterizing crystalline solid forms of substances used in pharmaceuticals, nutraceuticals, and/or dietary supplements. Alternatively, a POSA could have had a master's degree or a Ph.D. in chemistry or a closely related discipline and at least 2 years of experience crystallizing and characterizing crystalline solid forms of substances used in pharmaceuticals, nutraceuticals, and/or dietary supplements.

Alternatively, a POSA could have had a Ph.D. in chemistry, or a similar field, with 5 or more years of experience in academia or industry focused on crystallography and its methods of analysis (some of those five years could be spent as part of the Ph.D. program, for instance, but additional experience is needed to be considered a POSA). The methods of analysis can include X-ray powder diffraction ("XRPD"), but are not limited to XRPD.

**B4. VALIDITY** 

#### 4.3 INVALIDITY - ANTICIPATION FOR PUTTING INVENTION "ON SALE"

A patent claim is invalid if the claimed invention was on sale more than one year before its patent application was filed. Whether a claimed invention was on sale must be determined on a claim-by-claim basis.

The '058 Patent, e.g. the Form I Patent, originates from a patent application filed on July 24, 2014, and so their critical date is July 24, 2013.

The '872 Patent, e.g. the Form II Patent, originates from a patent application filed on March 9, 2015, and so its critical date is March 9, 2014.

To show a claim is invalid for being on sale, which means it was offered for sale or sold, Elysium must prove by clear and convincing evidence that, before the applicable critical date, an embodiment of the claimed invention was both (1) the subject of a commercial offer for sale or sold, and (2) ready for patenting.

A commercial offer for sale was made if another party could make a binding contract by simply accepting the offer. An invention was subject to an offer for sale if the claimed invention was embodied in an actual product and that product was commercially sold or offered for sale, even if it was done confidentially. It is not required that a sale was made.

The invention must have been ready for patenting at the time of the sale or offer for sale.

A claimed invention is ready for patenting when there is reason to believe it would work for its intended purpose. An invention is ready for patenting either when it is reduced to practice or

when the inventor has prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person of ordinary skill in the art to practice the invention. An invention is reduced to practice when it has been (1) constructed or performed within the scope of the patent claims, and (2) determined that it works for its intended purpose.

### **B4. VALIDITY**

### 4.4 INVALIDITY—ANTICIPATION BY PRIOR ART

In order for someone to be entitled to a patent, the invention must be "new." If a claimed invention is not new, it is said to be anticipated. Elysium contends that the Asserted Claims are invalid because the claimed inventions are anticipated. Elysium must prove anticipation by clear and convincing evidence, i.e., the evidence must demonstrate that there is a high probability that the claims are anticipated.

Specifically, Elysium contends that International Patent Application Publication No. WO 2015/186068, entitled "Preparation and Use of Crystalline Beta-D Nicotinamide Riboside" and listing "GlaxoSmithKline Intellectual Property (No.2) Limited" as its applicant, anticipates the Asserted Claims of the '058 and patent. This reference is referred to by the parties as the "GSK Reference."

Elysium contends that the GSK Reference is prior art that can be considered in determining whether the Asserted Claims of the '058 patent are anticipated. Specifically, Elysium contends that the GSK Reference is prior art because it is a published patent application that names another invention that was filed before the filing date of the '058 Patent. The effective filing date for the '058 Patent is July 24, 2014.

Elysium must prove by clear and convincing evidence that the GSK Reference is prior art.

Anticipation must be determined on a claim-by-claim basis. Elysium must prove by clear and convincing evidence that all of the requirements or elements of a claim are present in the GSK Reference and are arranged or combined in the same way as recited in the claim. You may

not combine other items of prior art with the GSK Reference to find anticipation. To anticipate the invention, the GSK Reference does not have to use the same words as the claim, but all of the requirements of the claim must have been disclosed and arranged as in the claim. The claim requirements may either be disclosed expressly or inherently—that is, necessarily implied—such that a person having ordinary skill in the art in the technology of the invention, looking at that one reference, could make and use the claimed invention.

In determining whether the GSK Reference anticipates a patent claim, you should take into consideration not only what is expressly disclosed in the GSK Reference, but also what is inherently present or disclosed in it or inherently results from its practice. Prior art inherently anticipates a patent claim if the missing element or feature would necessarily and inevitably result each and every time, without fail, from what the single item of prior art teaches to persons of ordinary skill in the art. Evidence of even one failure to result in the missing element or feature means that inherent anticipation cannot be shown. A party claiming inherent anticipation must prove that the allegedly inherent element or feature necessarily is present by clear and convincing evidence. Evidence outside of the prior art reference itself may be used to show that elements that are not expressly disclosed in the reference are inherent in it. To be inherent, the feature that is alleged to have been inherent must necessarily have existed in the prior art reference. The fact that the feature is likely to have existed is not sufficient. It is not required, however, that persons of ordinary skill recognize or appreciate the inherent disclosure at the time the prior art was first known or used. Thus, the prior use of the patented invention that was unrecognized and unappreciated can still be an invalidating anticipation, provided the allegedly inherent feature was necessarily present in the reference.

### **B4. VALIDITY**

#### 4.6 INVALIDITY – WRITTEN DESCRIPTION

The patent law contains certain requirements for the part of the patent called the specification. The "written description" requirement is designed to ensure that the inventor was in possession of the full scope of claimed invention as of the patent's effective filing date. The written description requirement exists because patents are part of a bargain between the American people and inventors in exchange for inventors providing a written application with claims that fully inform the public of the new invention and what the inventor thinks is his or her own invention, the inventor gets a monopoly on the claimed invention for the life of the patent.

Elysium contends that the Asserted Claims are invalid because the specification of each Asserted Patent does not contain an adequate written description of the inventions claimed in the Asserted Claims. To succeed, Elysium must show by clear and convincing evidence that a person having ordinary skill in the art reading the patent specification as of its effective filing date would not have recognized that it describes the full scope of the invention as claimed. If a patent claim lacks adequate written description, it is invalid.

The effective filing date for the '058 Patent is July 24, 2014.

The effective filing date for the '872 Patent is March 9, 2015.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent as of the effective filing date. The specification must describe the full

scope of the claimed invention, including each element thereof, either expressly or inherently. A claimed element is disclosed inherently if a person having ordinary skill in the field as of the effective filing date would have understood that the element is necessarily present in what the specification discloses. It is not sufficient that the specification discloses only enough to make the claimed invention obvious to the person having ordinary skill.

The written description does not have to be in the exact words of the claim. The requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent specification. Adequate written description does not require either examples or an actual reduction to practice of the claimed invention(s). However, a mere wish or plan for obtaining the claimed invention(s) is not adequate written description. Rather, the level of disclosure required depends on a variety of factors, such as: the nature and scope of the patent claims; the existing knowledge in the particular field; the extent and content of the prior art; the complexity, predictability, and maturity of the science or technology at issue; and other considerations appropriate to the subject matter.

The issue of written description is decided on a claim-by-claim basis, not as to the entire patent or groups of claims.

**B4. VALIDITY** 

### 4.7 INVALIDITY – INDEFINITENESS

Elysium also contends that the Asserted Claims are invalid because they are indefinite.

The definiteness requirement focuses on whether the claims, as interpreted in view of the written description, adequately perform their function of notifying the public of the scope of the patentee's right to exclude. A patent is invalid for indefiniteness if its claim, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

In other words, a patent claim is invalid as indefinite when a person or ordinary skill in the art reading the claim in the context of the written description would be unable to determine what the claim covers and what the claim does not cover. **B4. VALIDITY** 

### 4.8 INVALIDITY - ENABLEMENT

A patent must disclose sufficient information to enable or teach persons of ordinary skill in the field of the invention to make and use the full scope of the claimed invention without undue experimentation. This requirement is known as the enablement requirement. If a patent is not enabled, it is invalid.

Elysium contends that the Asserted Claims of the Asserted Patents are invalid for lack of enablement. To succeed, Elysium must show by clear and convincing evidence that the patent specification does not contain a sufficiently full and clear description to have allowed POSA to make and use the full scope of the claimed invention without undue experimentation. The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be "unduly extensive." Some amount of experimentation to make and use the invention is allowable. In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors, including:

- (1) the time and cost of any necessary experimentation;
- (2) how routine any necessary experimentation is in the field;
- (3) the presence or absence of working examples in the patent;
- (4) the amount and sufficiency of guidance presented in the patent;
- (5) the nature and predictability of the field;

- (6) the level of ordinary skill in the field; and
- (7) the breadth of the claims.

The above list of factors are neither mandatory nor exclusive, and no one or more of the above factors is alone conclusive. Rather, you must make your decision about whether or not the degree of any required experimentation is undue based upon all of the evidence presented to you. You should weigh these factors, and any other evidence related to this issue, and determine whether or not, in the context of this invention and the state of the art at the time of the applicable effective filing date, POSA would need to experiment unduly to make and use the full scope of the claimed invention claimed in the Asserted Patents.

### 6.1 DAMAGES—IN GENERAL AND BURDEN OF PROOF

I will instruct you about the measure of damages. By instructing you on damages, I am not suggesting which party should win on any issue. If you find that Elysium infringed any valid claim of the '058 Patent or '872 Patent, you must then determine the amount of money damages to be awarded to Grace to compensate it for the infringement.

The amount of those damages must be adequate to compensate Grace for the infringement, but in no event may the damages award be less than a reasonable royalty. You should keep in mind that the damages you award are meant to compensate the patent holder and not to punish an infringer.

Grace has the burden to persuade you of the amount of its damages by a preponderance of the evidence. In other words, you should award damages that Grace more likely than not suffered. Grace is not entitled to damages that are remote or speculative.

If you find that Elysium has not infringed any valid claim of the patents, then you should not consider the damages issue because Grace is not entitled to any damages. If you find that Elysium has shown all of the Asserted Claims to be invalid, then you should not consider the damages issue because Grace is not entitled to any damages.

There are different types of damages that Grace may be entitled to recover Grace proves that it is owed damages. In this case, Grace seeks a reasonable royalty. A reasonable royalty is defined as the amount of money that would have been agreed upon in the hypothetical

negotiation between Grace, on the one side, and Elysium, on the other side, as a fee for the use of the invention before the infringement began.

### 6.8 REASONABLE ROYALTY—DEFINITION

If you find that a patent claim is infringed and not invalid, Grace is entitled to at least a reasonable royalty to compensate it for that infringement.

The reasonable royalty award must be based on the incremental value that the patented invention adds to the end product. When the infringing product has both patented and unpatented features, measuring this value requires a determination of the value added by the patented features or other factors such as marketing or advertising, or Elysium's size or market position. The ultimate combination of royalty base and royalty rate must reflect the value attributable to the infringing features of the product and no more.

In other words, the reasonable royalty award must be based on the incremental value that Grace's patents add to the accused product. This is called "apportionment." A damages theory that is dependent on a comparable license (or a comparable negotiation) may in some cases have "built-in apportionment." Built-in apportionment assumes that the negotiators of a comparable license settled on a royalty rate and royalty base combination embodying the value of the asserted patents. A party relying on a sufficiently comparable license therefore can adopt the comparable license's royalty rate and royalty base without further apportionment and without proving that the infringing feature was responsible for the entire market value of the accused product. For built in apportionment to apply, however, the comparable license must be sufficiently comparable to the one that would result from the hypothetical negotiation between Grace and Elysium. There are many acceptable methods of calculating a reasonable royalty,

including for example the hypothetical negotiation approach, the market or comparable license approach, and the cost approach, each of which I will explain in more detail.

### 6.9 REASONABLE ROYALTY—THE HYPOTHETICAL NEGOTIATION APPROACH

Under the hypothetical negotiation approach, a reasonable royalty is defined as the amount of money that would have been agreed upon in the hypothetical negotiation between the parties as a fee for the use of the invention just before the infringement began. In considering this hypothetical negotiation, you should focus on what the expectations of the patent holder and the alleged infringer would have been had they entered into an agreement at that time, and had they acted reasonably in their negotiations.

Under the hypothetical negotiation approach, you must assume that both parties believed the patent was valid and infringed and that both parties were willing to enter into an agreement. The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred. Evidence of things that happened after the infringement first began can be considered in evaluating the reasonable royalty only to the extent that the evidence aids in assessing what royalty would have resulted from a hypothetical negotiation just prior to the first infringement. An infringer may be liable for reasonable royalty damages that exceed the amount that the infringer could have paid to avoid infringement, although you may consider the amount it would have paid to avoid infringement in considering what royalty rate would have been agreed-to in a hypothetical negotiation.

You should consider all the facts known and available to the parties at the time the infringement began.

# 6.10 REASONABLE ROYALTY—RELEVANT FACTORS IF USING THE HYPOTHETICAL NEGOIATION APPROACH

In determining the reasonable royalty, you should consider all of the facts known and available to the parties at the time that the infringement began.

You may use the following fifteen *Georgia-Pacific* factors to make this determination.

Not all are necessarily applicable. Some may tend to increase the royalty, while others could be neutral or tend to decrease it. These factors are as follows:

- 1. The royalties received by Grace for the licensing of the patents-in-suit, proving or tending to prove an established royalty.
- 2. The rates paid by Elysium for the use of other patents comparable to the asserted patent.
- 3. The nature and scope of the license, such as whether the license is exclusive or nonexclusive or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
- 4. Grace's established policy and marketing program to maintain its patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.

- 5. The commercial relationship between Grace on one hand and Elysium on the other, such as whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter.
- 6. The effect of selling the patented specialty in promoting sales of other products of Elysium; the existing value of the invention to Grace as a generator of sales of its non-patented items; and the extent of such derivative or convoyed sales.
- 7. The duration of the patents-in-suit and the term of the license.
- 8. The established profitability of the product made under the patents-in-suit, its commercial success, and its current popularity.
- 9. The utility and advantages of the patented property over the old modes or devices, if any, that had been used for working out similar results.
- 10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by Elysium, and the benefits to those who have used the invention.
- 11. The extent to which Elysium has made use of the invention, and any evidence probative of the value of that use.

- 12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
- 13. The portion of the realizable profits that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, or business risks, or significant features or improvements added by Elysium.
- 14. The opinion testimony of qualified experts.
- 15. The amount that Grace (licensor) and Elysium (licensee) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount that a prudent licensee, who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention, would have been willing to pay as a royalty and yet be able to make a reasonable profit, and which would have been acceptable by a prudent patent owner who was willing to grant a license.

No one factor is conclusive and you can and should consider the evidence that has been presented to you in this case on each of these factors. You may also consider any other factors which in your mind would have increased or decreased the royalty Elysium would have been willing to pay and Grace would have been willing to accept, acting as normally prudent businesspeople. The final factor establishes the framework which you should use in determining a reasonable royalty.

# 6.11 REASONABLE ROYALTY—THE MARKET APPROACH / USE OF COMPARABLE LICENSE AGREEMENTS

As I mentioned previously, another method by which to value a reasonable royalty is the market approach. The market approach values asserts based on comparable transactions such as comparable license agreements, which are one factor that may inform your decision as to the proper amount and form of the reasonable royalty award, similar to the way in which the value of a house is determined relative to comparable houses sold in the same neighborhood.

In other words, when determining a reasonable royalty, you may consider evidence concerning the amounts that other parties have actually paid for rights to the patents in question, or for rights to similar technologies. A license agreement need not be perfectly comparable to a hypothetical license that would be negotiated between Grace and Elysium in order for you to consider it. However, if you choose to rely upon evidence from any other license agreements, you must account for any differences between those licenses and the hypothetically negotiated license between Grace and Elysium, in terms of the technologies, economic circumstances of the contracting parties, as well as the scope and structure of the comparable agreement when you make your reasonable royalty determination.

### 6.12 REASONABLE ROYALTY—

### THE COST APPROACH / AVAILABILITY OF NON-INFRINGING SUBSTITUTES

The cost approach is yet another type of analysis that may be used to determine that appropriate reasonable royalty. Using this approach, in determining a reasonable royalty, you may also consider evidence concerning the availability and cost of acceptable non-infringing substitutes that do not infringe the patented invention.

However, reasonable royalty damages are not capped at the cost of implementing the cheapest available, acceptable, noninfringing alternative. To the contrary, an infringer may be liable for damages, including reasonable royalty damages, that exceed the amount that the infringer could have paid to avoid infringement.

### 6.15 DAMAGES—REASONABLE ROYALTY – ENTIRE MARKET VALUE RULE

A multi-component product may have both infringing and non-infringing components. In such products, royalties should be based not on the entire product, but instead on the "smallest salable unit" that practices the patent and has close relation to the claimed invention. Where the smallest salable unit is, in fact, a multi-component product containing several non-infringing features with no relation to the patented feature, damages must only be based on the portion of the value of that product attributable to the patented technology. This may involve estimating the value of a feature that may not have ever been individually sold.

The entire market value rule is a narrow exception to this general rule. In order to recover damages as a percentage of revenues or profits attributable to the entire product, Grace must establish that it is more likely than not that the patented feature drives the demand for an entire multi-component product such that it creates the basis for customer demand or substantially creates the value of the product.

A damages theory that is dependent on a comparable license (or a comparable negotiation) may in some cases have "built-in apportionment."

Built-in apportionment effectively assumes that the negotiators of a comparable license settled on a royalty rate and royalty base combination embodying the value of the asserted patents.

A party relying on a sufficiently comparable license therefore can adopt the comparable license's royalty rate and royalty base without further apportionment and without proving that the infringing feature was responsible for the entire market value of the accused product.

# 6.16 DATE OF COMMENCEMENT OF DAMAGES AND PROVISIONAL RIGHTS DAMAGES

In determining the amount of damages, you must determine when the damages began.

Damages commence on the date that Elysium both infringed and was notified of the alleged infringement of the Asserted Patents.

Grace and Elysium agree that date was August 21, 2020.

In addition, Grace seeks a type of damages called provisional damages. By statute, provisional damages are available from the date a patent application was published until the date the patent issues. In this case, that period runs from July 2017 to January 29, 2019.

Provisional damages are awarded where the alleged infringer had notice of the published application, and the invention claimed in the published application is substantially the same as the invention claimed in the issued patent. Grace must show it is entitled to provisional rights damages by a preponderance of the evidence.

#### **B7. DELIBERATIONS**

#### 7. DELIBERATIONS

I have completed my instructions on the law. All of the instructions I gave you today—as well as earlier this week—still apply, and you will have a copy of the instructions with you in the jury room.

I will finish by explaining some things about your deliberation in the jury room, and your possible verdict.

When you retire to the jury room to deliberate, you may take with you these instructions, your notes, and the exhibits that the Court has admitted into evidence. You should select one member of the jury as your foreperson. That person will preside over the deliberations and speak for you here in open court.

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way.

Your second duty is to take the law that I give you, apply it to the facts, and decide if, under the appropriate burden of proof, the parties have established their claims. It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not let any bias, sympathy or prejudice that you may feel toward one side or the other influence your decision in any way.

As jurors, you have a duty to consult with each other and to deliberate with the intention of reaching a verdict. Each of you must decide the case for yourself, but only after a full and impartial consideration of all of the evidence with your fellow jurors. Listen to each other carefully. In the course of your deliberations, you should feel free to re-examine your own views and to change your opinion based upon the evidence. But you should not give up your honest convictions about the evidence just because of the opinions of your fellow jurors. Nor should you change your mind just for the purpose of obtaining enough votes for a verdict. Remember at all times that you are not partisans. You are judges of the facts. Your sole interest is to seek the truth from the evidence in the case. What the verdict shall be is your sole and exclusive duty and responsibility.

When you start deliberating, do not talk to the jury officer, to me or to anyone but each other about the case. During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. If you have any questions or messages for me, you must write them down on a piece of paper, have the foreperson sign them, and give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you.

During your deliberations, you may not use any electronic device or media, such as any electronic device or media, such as a cell phone, smartphone, iPhone, iPad, tablet, computer, the Internet, any Internet service, any text or instant messaging service, Internet chat room, or blog

or website such as Facebook, LinkedIn, YouTube, Instagram, WeChat, WhatsApp, Snapchat, or Twitter, to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict. In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

You may not use these electronic means to investigate or communicate about the case because it is important that you decide this case based solely on the evidence presented in this courtroom. Information on the internet or available through social media might be wrong, incomplete, or inaccurate. Information that you might see on the internet or on social media has not been admitted into evidence and the parties have not had a chance to discuss it with you. You should not seek or obtain such information and it must not influence your decision in this case. One more thing about messages: never write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. Your votes should stay secret until you are finished.

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, each juror must agree to the verdict. Your verdict must be unanimous.

A form of verdict has been prepared for you. It has a series of questions for you to answer. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will fill it in, and have your foreperson date and sign the form.

You will then return to the courtroom and your foreperson will give your verdict. Unless I direct

you otherwise, do not reveal your answers until you are discharged. After you have reached a verdict, you are not required to talk with anyone about the case unless I order you to do so.

Once again, I want to remind you that nothing about my instructions and nothing about the form of verdict is intended to suggest or convey in any way or manner what I think your verdict should be. It is your sole and exclusive duty and responsibility to determine the verdict.

### C.1 Appendix—GLOSSARY

Some of the terms in this glossary will be defined in more detail in the instructions you are given. The definitions in the instructions must be followed and must control your deliberations.

**Abstract:** A brief summary of the technical disclosure in a patent to enable the U.S. Patent and Trademark Office and the public to determine quickly the nature and gist of the technical disclosure in the patent.

**Amendment:** A patent applicant's change to one or more claims or to the specification either in response to an office action taken by a Patent Examiner or independently by the patent applicant during the patent application examination process.

**Assignment:** A transfer of patent rights to another called an "assignee" who upon transfer becomes the owner of the rights assigned.

Claim: Each claim of a patent is a formal definition of an invention and appears at the end of the specification in a separately numbered paragraph. In concept, a patent claim marks the boundaries of the patent in the same way that a legal description in a deed specifies the boundaries of land, i.e. similar to a landowner who can prevent others from trespassing on the bounded property, the inventor can prevent others from using what is claimed. claims may be independent or dependent. An independent claim stands alone. A dependent claim does not stand alone and refers to one or more other claims. A dependent claim incorporates whatever the other referenced claim or claims say.

**Drawings:** The drawings are visual representations of the claimed invention contained in a patent application and issued patent, and usually include several figures illustrating various aspects of the claimed invention.

Elements: The required parts of a device or the required steps of a method in a patent claim.

Embodiment: A product or method that contains or "embodies" the claimed invention.

**Examination:** Procedure before the U.S. Patent and Trademark Office whereby a Patent Examiner reviews the filed patent application to determine if the claimed invention is patentable.

**Filing Date:** Date a patent application has been submitted to the U.S. Patent and Trademark Office.

Limitation: Synonym for "element."

Office Action: A written communication from the Patent Examiner to the patent applicant in the course of the application examination process.

**Patent:** A patent is an exclusive right granted by the U.S. Patent and Trademark Office to an inventor to prevent others from making, using, offering to sell, or selling an invention within the

United States, or from importing it into the United States, during the term of the patent. When the patent expires, the right to make, use or sell the invention is dedicated to the public. The patent has three parts, which are a specification, drawings and claims. The patent is granted after examination by the U.S. Patent and Trademark Office of a patent application filed by the inventor which has these parts, and this examination is called the prosecution history.

Patent and Trademark Office (Patent Office or PTO): An administrative branch of the U.S. Department of Commerce that is charged with overseeing and implementing the federal laws of patents and trademarks. It is responsible for examining all patent applications and issuing all patents in the United States.

**Prosecution History (File Wrapper):** The prosecution history is the complete written record of the proceedings in the Patent Office from the initial application to the issued patent. The prosecution history includes the office actions taken by the Patent Office and the amendments to the patent application filed by the applicant during the examination process.

Requirement: Synonym for "element."

**Royalty:** A royalty is a payment made to the owner of a patent by a non-owner in exchange for rights to make, use or sell the claimed invention.

**Specification:** The specification is a required part of a patent application and an issued patent. It is a written description of the invention and of the manner and process of making and using the claimed invention, and can include drawings/figures. See **Patent**.

### C.2 Appendix—COURT'S CLAIM INTERPRETATIONS

The following language in the patent claims involved in this case has been interpreted or agreed upon as shown below. You must accept these interpretations as correct.

TERM	Construction
"Crystalline Form I of nicotinamide riboside chloride according to formula I" ['058 patent"]	Crystalline Form I of nicotinamide riboside chloride, according to Formula I, which can be identified by one or more of the analytical methods described in the specification
"crystalline Form II of nicotinamide riboside chloride" ['872 patent]	Crystalline Form II of nicotinamide riboside chloride, which can be identified by one or more of the analytical methods described in the specification
"characterized by"	identifiable by reference to
"A method for increasing nicotinamide adenine dinucleotide (NAD) concentration in a subject in need thereof"	Limiting preamble; ordinary, customary meaning
"A method for supplementing the diet of a subject" / "supplementing the diet"	Limiting preamble; ordinary, customary meaning
"pharmaceutically acceptable excipient"	An excipient that, within the scope of sound medical judgment, is suitable for contact with the tissues of human beings and animals without excessive toxicity, irritation, allergic response, or other problem complications commensurate with a reasonable benefit/risk ratio
"pharmaceutically acceptable amount"	An amount that, within the scope of sound medical judgment, is suitable for contact with the tissues of human beings and animals without excessive toxicity, irritation, allergic response, or other problem complications commensurate with a reasonable benefit/risk ratio
"substantially as shown"	largely but not wholly